SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING JUNE 26-27, 2000

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Monday, June 26, 2000 at 1:30 p.m. Eastern Daylight Time (EDT) and on Tuesday, June 27, 2000 at 9 a.m. EDT as part of the Sixth NELAC Annual Meeting in Williamsburg, VA. The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency (EPA) Region 3. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss the following sections from Chapter 5 of the NELAC Standards: D.5 Air Testing, D.4 Radiochemical Testing, D.3 Microbiology Testing, Section 5.12 Records and Legal Chain of Custody Protocols, Appendix E, D.2 Toxicity Testing, D.1 Chemical Testing, the Glossary, and Sections 5.0-5.16.*

INTRODUCTION - MONDAY JUNE 26, 2000

Mr. Slayton welcomed the attendees and the committee members, who were all present in person or by teleconference, introduced themselves. Mr. Slayton stated that his term and Ms. Mary Bruch's term as committee members are expiring. Mr. Scott Siders will become the chair of the QS Committee and Ms. Marty Casstevens will be joining the committee.

The session facilitator reviewed the ground rules and requested that attendees complete evaluation forms for this session. The chair discussed the challenges of balancing the stronger standards requested by regulators, the flexibility desired by laboratories and the need for writing clear standards.

TOPICS OF DISCUSSION

D.5 AIR TESTING

The chair briefly reviewed the history of D.5 Air Testing, which was not approved at the Fifth NELAC Annual Meeting (NELAC V). Since then, a subcommittee was formed to revise D.5, which is included in the Proposed Changes to NELAC Standards (June 26, 2000).

A commenter suggested that D.5 be tabled until the standards are more consistent, harmonious, broadly applicable (e.g., for emission stack testing in the field). He also mentioned an inconsistency in the standards with stack test trailers and he would like it clarified to which methods the standards apply. The committee responded that these standards are not method-specific, encompass ambient testing, are not strictly for source emissions, do not supercede any method or regulatory requirement, and are designed to be minimum rules of quality for any method in the absence of any other regulations. One commenter provided D.5.8.d as an example on the scope of D.5: "blank every 20 samples" is not clear enough. The committee responded that "matrix" is defined in the glossary and D.5.8.d. has a caveat that clarifies the point.

Attendees commented that Air does not belong as a separate appendix as it mixes disciplines and matrices. However, another commenter is in favor of a separate section for air because laboratories have been confused by trying to use D.1 Chemical Testing standards for air.

There was extensive discussion on how to revise the introduction to clarify the scope of D.5. For example, one recommendation was to indicate in the introduction that this section is not presently relevant for stack emissions, with the understanding that it can be revised in the future. In addition, "laboratory" doesn't necessarily mean a laboratory building. For example, the standard would apply to a suma canister that is transported to a laboratory for further analysis (i.e., for the determinative step). The background for this is in ISO 25.

Proposed language for the scope of D.5:

> **These standards shall apply to samples that are submitted to a laboratory for the purpose of analysis. They do not apply to field activities such as source air emission measurements or the use of continuous analysis devices.**

D.5.1.c Surrogates and D.5.1.d Matrix Spikes

One commenter indicated that these two sections need specific project protocol.

D.5.2 Matrix Spike Duplicates

The following change was proposed and accepted by consensus:

> **Matrix Spike Duplicates (MSDs) or Laboratory Duplicates – Shall be analyzed at a minimum of 1 in 20 samples per sample batch. The laboratory shall document their procedure to select the use of appropriate types of spikes and duplicates. The selected samples(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in the spikes and duplicates may indicate a problem with the sample composition and shall be reported to the client.**

D.5.1.b.1

> **Change "limat" to "limit."**

D.4 RADIOCHEMICAL TESTING

The chair provided history of the work group that revised the standards based on comments from inspectors. The new version is clearer and improves the ability to audit.

A discussion on "batch acceptance" resulted in the following changes to D.4.1.a.1, D.4.1.b.1, D.4.1.b.2, and D.1.1.b.1 of the proposed standards.

> **D.4.1.a.1 The results of this analysis shall be one of the quality control measures to be used to assess the batch.**

> **D.4.1.b.1 The results of this analysis shall be one of the quality control measures to be used to assess the batch.**

D.4.1.b.2 The results of this analysis shall be one of the quality control measures to be used to assess the batch.

That discussion resulted in moving back to D.1.1.b.1 "laboratory control samples" in Chemical Testing.

D.1.1.b.1 The results of these samples shall be used to assess the batch.

There was additional discussion for the glossary on "analytical batch" vs. "preparatory batch." The Committee's conclusion is that the intent was referring to analytical batch. Therefore, the glossary should not be changed.

D.4.1.b.2

There is an additional change to D.4.1.b.2

Matrix Spike - Shall be performed at a frequency of one per preparation batch for those methods which do not utilize an internal standard or carrier, for which there is a chemical separation process, and where there is sufficient sample to do so. The exceptions are gross alpha, gross beta and tritium which shall require matrix spikes for aqueous samples. The results of this analysis shall be one of the quality control measures to be used to assess batch acceptance. The matrix spike result shall be assessed against the specific acceptance criteria [see 5.10.1.2.b)18] specified in the laboratory method manual [see 5.10.1.2]. When the specified matrix spike acceptance criteria is not met, the specified corrective action and contingencies [see 5.10.1.2.b)19 and 20] shall be followed. The occurrence of a failed matrix spike acceptance criteria and the actions taken shall be noted in the laboratory report [see 5.13.a)10]. The lack of sufficient sample aliquot size to perform a matrix spike shall be noted in the laboratory report.

D.4.4.a.1

The following change was proposed and accepted by consensus:

Given that activity detection efficiency is independent of sample activity at all but extreme activity levels, the requirements of subsection f, h and i of 5.9.4.2.1 are not applicable to radiochemical method calibrations except mass attenuation in gas-proportional counting and sample quench in liquid scintillation counting.

Calibration Software

One attendee asked if the standards will address the use of new software for calibration of gamma spectrometry. The committee requested information, which the commenter will send with specific proposed language to consider in the future.

D.4.8.c

The discussion addressed clarifying "each day of use." The following change was drafted:

For alpha spectrometry systems, background check measurements shall be performed except when using the electro-plating method of sample preparation.

D.3 MICROBIOLOGY

D.3.1.a.2

The following change was drafted:

> **Analyze (culture) a known negative control using a non-target organism, as a procedural control of the method for each commercial lot of selective media or batch of media prepared in the lab.**

D.3.1.a.3

There was no consensus after discussing this section because drinking water representatives thought the language was redundant, but waste water representatives thought it was important. Barring consensus, the committee agreed to leave it as proposed.

D.3.2.a

The discussion on this section focused on the proposed change of "at least 5% of the suspected positive samples shall be duplicated" to the proposed change of "at least 10% of the samples shall be duplicated." Commenters considered 10% to be high and/or arbitrary and the intent of the section did not match the proposed change. The entire section was rewritten as follows.

> **Duplicates - The laboratory must demonstrate its ability to duplicate the results by analyzing duplicative samples or by performing a positive control in duplicate at least once per month.**

D.3.6.c

The committee reached consensus on the following change:

> **Distilled water, deionized water or reverse-osmosis produced water free from bactericidal and inhibitory substances (e.g., demonstrated with the Water Suitability test) shall be used in the preparation of media, solutions, and buffers. The quality of the water shall be monitored for chlorine residual, specific conductance, and heterotrophic bacteria plate count on a monthly frequency (when used) and analyzed for metals yearly and evaluated according to the required method. Records shall be maintained on all activities.**

D.3.6.f

There was extensive discussion about inhibitory residue tests. This issue is not about media or detergent, but about test conditions. Comments on this issue included options that laboratories use. For example, residue tests can be done by another laboratory or laboratories can perform spot checks on every batch so that they don't have to send tests out to another laboratory. There were also comments on laboratory-grade detergent and certification from detergent manufacturers. One commenter suggested moving D.3.6.f (in approved standards) to D.3.8. and adding it as "h." The text of D.3.6.f from the approved standard as well as the proposed language for the new D.3.8.h follows.

> **D.3.8.h.**
>
> **1) Glassware shall be tested for possible presence of residues which may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test each time the lab changes the lot of detergent, personnel, or washing procedures.**
>
> **2) Each batch of washed glassware shall be tested for possible acid or alkaline residue by testing one piece of glassware with a suitable pH indicator such as bromthymol blue.**

D.3.8.c.2

The discussion on this section focused on whether or not both biological and chemical indicators are needed. One commenter suggested clarifying the language to require biological indicators and chemical

indicators only if appropriate (even when there is continuous temperature control). The consensus was that "appropriate" is not helpful. The committee resolved that both biological and chemical indicators are needed. The entire proposed section has been rewritten. The original proposed section and the revisions follow.

> **Demonstration of sterilization shall be provided by a continuous temperature recording and through the use of appropriate biological indicators at least once each month of use except when temperature recording is not available and then the frequency of biological indicator use shall be once each week.**

D.3.6.e
One commenter stated that D.3.6.e is a continuation of positive and negative controls and is therefore redundant with D.3.1. The committee resolved to review the chapter for redundancies.

Voting Strategy

The chair explained that voting will be handled by separating the points that have elicited extensive discussion (e.g., detergent residue and quality control checks on water) from larger blocks of text.

INTRODUCTION - TUESDAY JUNE 27,2000

The attendees were welcomed by Mr. Slayton, who then reviewed the agenda, reminded the attendees of the ground rules, and asked them to review the final wording for the proposed changes for D.3 Microbiological Testing (from yesterday's session) before the conference voting session. The committee members then introduced themselves.

TOPICS OF DISCUSSION

Appendix E Legal Chain of Custody Protocols

There was extensive discussion about Appendix E. Several people commented that Appendix E is misleading and could create an unnecessary burden even though there are examples of higher custody requirements than what is proposed. Commenters indicated that if Appendix E is not deleted, it needs to be client-focused (i.e., for attorneys) and project specific. States and Accrediting Authorities need legal chain of custody in the standard, but it doesn't need to be as specific as the proposed appendix. Discussion also included whether or not subsamples and sample digestates should be held to the same high level of custody that applies to the sample.

The consensus was to leave this issue flexible and let attorneys decide what they need (although attorneys may not always be present). Appendix E will be deleted. The contents of Appendix E will not be provided on the NELAC Web site as additional information because past feedback has indicated that it may be interpreted by some as part of the standard.

5.12 Records
The consensus on this section is to correct the grammar, delete the reference to Appendix E, and add reference documents.

There are two levels of sample handling: 1) sample tracking and 2) legal chain of custody protocols, which are used for evidentiary or legal purposes. All essential requirements for sample tracking (e.g., chain of custody form) are outlined in Sections 5.12.1, 5.12.2 and 5.12.3. If a client specifies that a sample will be used for evidentiary purposes, then a laboratory shall have a written SOP for how that laboratory will carry out legal chain of custody for example, ASTM D 4840-95 and Manual for the Certification of Laboratories Analyzing Drinking Water, March 1997, Appendix A.

5.12.3.3 Analytical Records

The following change was proposed and accepted by consensus:

Date of analysis and time of analysis is required if the holding time is 72 hours or less or when time critical steps are included in the analysis, e.g. extractions and incubations.

5.12.3.1.d Sample Handling

The following change was proposed and accepted by consensus:

The laboratory shall have documented procedures for the receipt and retention of test items, including all provisions necessary to protect the integrity of samples.

Sample Tracking Issues

This segment of the session concluded with a request for clarification on what NELAC calls sample tracking and whether a laboratory's SOP for chain of custody would meet the requirement. The Committee agreed. The chair explained that the term "legal chain of custody form," which is defined in the glossary, is used to clarify this issue.

D.2 Toxicity Testing

Pete DeLisle provided the background on changes made to this section in response to comments from VA, NJ, and CA and to bring out the essential QC requirements for toxicity testing in general as opposed to references to manuals.

The following sections were discussed. Subsequently, proposed language was offered and accepted by consensus.

D.2.1.a.2.iii

After 20 data points are collected for a test method and species, the control chart is maintained using only the 20 most recent data points, i.e., each successive mean value and control limit is calculated using only the last 20 values.

D.2.1.a.2.vi

In the case of reference toxicant data which fails to meet acceptance criteria, the results of environmental toxicity tests conducted during the affected period may be suspect and regarded as provisional. In this case the test procedure is examined for defects and the test repeated if necessary, using a different batch of organisms, as soon as possible or the data is qualified.

D.2.6.c and glossary term

Discussion was initiated on preparing synthetic water from groundwater and surface water. The consensus is a revision to D.2.6.c and the glossary as follows:

> **D.2.6.c Only reagent-grade water collected from distillation or deionization units (> 17 megohm resistivity) is used to prepare reagents.**

Action item: Forward the recommendation to **delete the term "synthetic dilution water" from the glossary** to the Program Policy and Structure Committee

D.2.8.h

The following change to the proposed standard was proposed and accepted by consensus:

> **The quality of the standard dilution water used for testing or culturing must be sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance. Water used for culturing and testing shall be analyzed for toxic metals and organics whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause, such as contaminated glassware or poor stock, can be identified. It is recognized that the analyte lists of some methods manuals may not include all potential toxicants, are based on estimates of chemical toxicity available at the time of publication and may specify detection limits which are not achievable in all matrices.**

D.2.8.i

The following change to the proposed standard was proposed and accepted by consensus:

> **For each new batch of food used for culturing and testing the performance of organisms fed with the new food shall be compared with the performance of organisms with a food of known quality in side-by-side tests. If the food is used for culturing, its suitability is determined using a short-term chronic test that measures the effect of food quality on growth or reproduction of each of the relevant test species in culture, using a minimum of four replicates with each food source. Where applicable, foods used only in chronic toxicity tests are compared with a food of known quality in side-by-side, multi-concentration chronic tests, using the reference toxicant regularly employed in the laboratory QA program. In the case of algae, rotifers or other cultured foods, which are collected as a continuous batch, the quality is assessed, using side-by-side tests as described above, each time new nutrient stocks are prepared, a new starter culture is employed or when a significant change in culture conditions occurs. The laboratory shall have written procedures for the statistical evaluation of food acceptance.**

One attendee had additional comments on behalf of a toxicologist regarding batches of food and how often it needs to be tested. The Committee suggested and the commenter agreed that the toxicologist should submit his/her comments directly to the Committee.

D.2.8.r

Consensus was not reached on this section. Resolving this issue is recorded as an action item.

D.2.8.w

After some discussion on this section, the consensus was "no change." The rationale is that if the method requires more stringent requirements, then the stricter requirements are followed.

D.1 CHEMICAL TESTING

D1.1.b.2

The following change to the proposed standard was proposed and accepted by consensus:

> **Matrix Spikes (MS) - Shall be performed at a frequency of one out of every 20 samples per matrix type prepared over time, except for analytes for which spiking solutions are not available such as, total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in a matrix spike may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the spike.**

D.1.1.b.4

The following change to the proposed standard was proposed and accepted by consensus:

> **If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components, the components coelute or components are incompatible, a representative number (at a minimum 10%) of the listed components may be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period, unless the spiking list is specified by the reference method.**

D.1.4.c

The following change to the proposed standard was proposed and accepted by consensus:

> **Detection limits must be determined each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis**

D.1.4.g

The following change to the proposed standard was proposed and accepted by consensus:

> **The test method's quantitation limits must be established and must be above the detection limits.**

D.1.6.3

The following change to the proposed standard was proposed and accepted by consensus:

The laboratory will verify the concentration of titrants in accordance with written laboratory procedures.

Method Detection Limits and Quantitation Limits

Comments initiated discussion on quantitation limits, method detection limits, etc. The Committee stated that the standard requires that the quantitation limit has to be above the detection limit. It is also required that sample results below the lowest calibration standard must be qualified (see 5.9.4.2.1.f). The laboratory selects their method for determining quantitation.

5.10.2.a.1 Test Methods

The following change to the proposed standard was proposed and accepted by consensus:

When the use of reference test methods for a sample analysis are mandated or requested, only those methods shall be used.

D.1

ELAB has submitted comments on D.1 and suggested rewording. ELAB has also submitted a paper on this issue. The Committee responded that there is not adequate time to address this new information in the current conference. Addressing this information is an action item for the Committee.

5.8

There was a recommendation from another committee to address demonstration of capability for example when a new instrument is brought on-line. The following proposed language will be a new "d" and the subsequent sections are lettered accordingly.

5.8.d

The following change to the proposed standard was drafted:

Before the analysis of any samples, the instruments used (e.g., GC, GC/MS, ICP, AA, spectrometer, etc.) shall be shown to have acceptable accuracy and precision. This is demonstrated by performing the procedures per Appendix C without sample extraction or digestion.

One attendee commented that many of the requirements of D.1 now appear in D.4. Some of the wording is the same and the changes were not made to carry the language consistently. The Quality System will need to review it; however, it is too late to address this issue for voting at NELAC VI. The committee views these as clarifications and will review the standards for those kinds of revisions in the future.

Glossary

The definition for "Quantitation Limits" was changed by the Program Policy and Structure Committee at this morning's session as follows:

Quantitation Limits: levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported at a specified degree of confidence. (NELAC)

In addition, the following recommendations will be forwarded to the Policy Program Structure Committee for detection limit and sample tracking:

Detection Limit: the lowest concentration or amount of the target analyte that can be identified, measured and reported with confidence that the analyte concentration is not a false positive value. See Method Detection Limit. (NELAC)

Sample Tracking: procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples. (NELAC)

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE MEETING
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Item No.	Action	Date to be Completed
1.	Forward the recommendation to the Program Policy and Structure Committee to delete the term "synthetic dilution water" in the glossary.	
2.	The committee will review the chapter for redundancies resulting from revisions.	
3.	Pete DeLisle will work with the commenter on D.2.8.r to draft new language.	
4.	Address ELAB's comments on D.1. ELAB has submitted suggested rewording and a paper on this issue.	

Attachment B

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QUALITY SYSTEMS COMMITTEE MEETING
JUNE 26-27, 2000

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